



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Dean L. Engelhardt et al.

Serial No. 08/479,997

Group Art Unit: 1656

Filed: June 7, 1995

Examiner: Scott W. Houtteman

Title: OLIGO- OR POLYNUCLEOTIDES, AND
OTHER COMPOSITIONS COMPRISING
PHOSPHATE MOIETY LABELED
NUCLEOTIDES

#39
D.80
3/23/01

**TRANSMITTAL
SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§1.56 & 1.97-1.98**

HON. COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Sir:

Transmitted herewith is an Information Disclosure Statement which is being filed in accordance with 37 C.F.R. §§ 1.56 and 1.97-1.98. The items listed on Form PTO-1449, a copy of which is enclosed, may be deemed to be pertinent to the above-identified application and are made of record to assist the Patent and Trademark Office in its examination of this application. The Examiner is respectfully requested to fully consider the items and to independently ascertain their teaching.

1. ☐ For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, an English language translation of that item or a portion thereof or a concise explanation of the relevance of that item is enclosed:
2. ☐ For each of the following items listed on the enclosed copy of form PTO-1449 that is not in the English language, a concise explanation of the relevance of that item is incorporated in the specification of the above-identified application.
3. ☐ Any copy of the items on the enclosed copy of Form PTO-1449 that is not enclosed with this Information Disclosure Statement was previously cited by or submitted to the Patent and Trademark Office in the prior ☐ Divisional or ☐ Continuation-In-Part application under 37 C.F.R. §1.60, U.S. Serial No. _____, filed _____.
4. ☐ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with:

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- ☐ 37 C.F.R. §1.97(b)(1), within three months of the filing date of the above-identified application.
- ☐ 37 C.F.R. §1.97(b)(2), within three months of the date of entry into the national stage as set forth in §1.491 in an international application.
- ☐ 37 C.F.R. §1.97(b)(3), before the mailing date of a first Office action on the merits.
5. ☐ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a Notice of Allowance (where there has been no prior final action), and is accompanied by one of the certifications pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below.
6. ☒ A fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a notice of allowance (where there has been no prior final action):
- ☐ A check in the amount of \$240.00 is enclosed in payment of the fee.
- ☒ Charge the fee to Deposit Account No. 05-1135, Order No. ENZ-5(D6)(C2)). A DUPLICATE COPY OF THIS SHEET IS ATTACHED.
7. ☐ A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(d), after the mailing date of a final action or a notice of allowance, whichever comes first, but before payment of the issue fee, and is accompanied by:
- a. one of the certification pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below; and
- b. the attached petition requesting consideration of this Information Disclosure Statement; and
- c. the fee due under 37 C.F.R. §1.17(i)(1) which is paid as set forth in paragraph 10 below.
8. ☐ A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with:
- a. ☐ 37 C.F.R. §1.313(b)(3), after the issue fee has been paid and information cited in this Information Disclosure Statement may render at least one claim unpatentable and is accompanied by the attached Petition To Withdraw Application From Issue;
- b. ☐ 37 C.F.R. §1.313(b)(5), after the issue fee has been paid and information cited in this Information Disclosure Statement is to be considered in a Continuation application upon abandonment of the instant application and is accompanied by the attached Petition To Withdraw Application From Issue.
- c. ☐ The fee due under 37 C.F.R. §1.17(i)(1) is paid as set forth in paragraph 10 below.

9. ☐ I hereby certify that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

☐ I hereby certify that no item of information in the Information Disclosure Statement filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

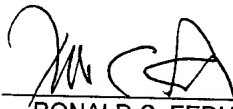
10. ☐ A check in the amount of \$130.00 is enclosed in payment of the fee due under 37 C.F.R. §1.17(i)(1).

☐ Charge the fee under 37 C.F.R. §1.17(i)(1) to Deposit Account No. 05-1135. Order No. _____ A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

☒ The Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. 05-1135. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,

Dated: March 15, 2001

By: 
RONALD C. FEDUS
Registration No. 32,567

Mailing Address:

ENZO DIAGNOSTICS, INC.
c/o Enzo Biochem, Inc.
527 Madison Avenue, 9th Floor
New York, New York 10022
Telephone: (212) 583-0100
Telefax: (212) 583-0150



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527 Madison Avenue, 9th Floor
New York, New York 10022
March 15, 2001

FILED VIA EXPRESS MAIL

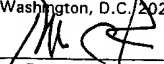
Hon. Commissioner of Patents and Trademarks
Washington, D.C. 20231

**SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§1.56 & 1.97-1.98**

Dear Sirs:

Pursuant to the provisions of 37 C.F.R. §§ 1.97-1.98, and in full compliance with their duty of disclosure under 37 C.F.R. §1.56, Applicants, through their attorney, are bringing the following twenty-two (22) documents to the attention of the U.S. Patent and Trademark Office and the Examiner handling their above-identified application:

1. Organic Chemistry of Nucleic Acids, Part B, Kochetkov, N.K. and Budovskii, E.I., Editors, Chapter 9, pages 449-477, Plenum Press, London and New York (1972) [Exhibit 1];
2. Armstrong, V. W. and Eckstein, F., "Interaction of substrate analogues with Escherichia coli DNA-dependent RNA polymerase," Eur. J. Biochem 70:33-38 (1976) [Exhibit 2];

EXPRESS MAIL CERTIFICATE	
"Express Mail" Label No.:	EL369155226US
Deposit Date:	March 15, 2001
I hereby certify that this paper and the attachments herein are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.110 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231	
 Ronald C. Fedus Reg. No. 32,567	MAR 15 2001 Date

3. Rozovskaya, T.A. et al., "Introduction of a fluorescent label at the 3'-OH end of DNA and the 3'-OH end of the growing RNA chain," Molkulyarnaya Biologiya 11(3):598-610 (1977)[Exhibit 3];
4. Petrov, A. I. And Sukhorukov, B.I., "Spin-labeled polyribonucleotides," Nucleic Acids Research 8(18):4221-4234 (1980) [Exhibit 4];
5. Hiratsuka, T. and Uchida, K., "Preparation and Properties of 2'(or 3')-O-(2,4,6-trinitrophenyl) Adenosine 5'-Triphosphate, An Analog of Adenosine Triphosphate," Biochimica et Biophysica Acta 320:635-647 (1973) [Exhibit 5];
6. Kourilsky, P. et al., GB-2,019,408 [Exhibit 6];
7. Bauman J.G.J. et al., "Rapid and high resolution detection of *in situ* hybridisation to polytene chromosomes using fluorochrome-labeled RNA," Chromosoma (Berl.) 84:1-18 (1981) [Exhibit 7];
8. Bauman J.G.G. et al., "Cytochemical hybridization with hybridization with fluorochrome-labeled RNA," J. Histochem. Cytochem 29:227-237 (1981) [Exhibit 8];
9. Broker T.R. et al., "Electron microscopic visualization fo tRNA genes with ferritin-avidin biotin labels," Nucleic Acids Research 5(2):363-384 (1978) [Exhibit 9];
10. Sodja A. and Davidson, N., "Gene mapping and gene enrichment by the avidin-biotin interaction: use of cytochrome-c as a polyamine bridge," Nucleic Acids Research 5(2):385-401 (1978) [Exhibit 10];
11. Daniel F.B. and Behrman, "Osmium (VI) Complexes of the 3',5'-Dinucleoside Monophosphates, ApU and UpA," Biochemistry 15(3):565-568 (1976) [Exhibit 11];
12. Ward D.C. et al., European Patent EP 0 063 879 [Exhibit 12];
13. Eberhard W. et al., "Galactopyranosyl-B(1-3')-ribonucleosides-structural evidence and synthesis," Nucleic Acids Research 9:15-19 (1981) [Exhibit 13];
14. Saffhill R. and Hall, J.J., "A Convenient Preparatin Of Isomerically Pure Nucleoside 5'-Monophosphates From Unprotected Nucleosides," Carbohydrates Nucleosides Nucleotides 8:573-583 (1981) [Exhibit 14];
15. Scherberg N.H., U.S. Patent No. 4,260,737 [Exhibit 15];
16. Kourilsky, P., German Patent DE 29 15 082 [Exhibit 16];
17. Halloran, M.J. et al., "The Preparation Of Nucleotide-Protein Conjugates: Carbodiimides As Coupling Agents," J. Immunology 96:373-378 (1966) [Exhibit 17];
18. Erlanger B.F. and Beiser, S.M., "Antibodies Specific For Ribonucleosides And Ribonucleotides And Their Reaction With DNA," Proc. Natl. Acad. Sci. 52:68-74 (1964); [Exhibit 18];
19. Suzuki S. et al., "The Binding Sites of Nucleosides or Nucleotides To

Diethylenetriaminicobalt (III)," Bioinorganic Chemistry 3:281-293 (1974).
[Exhibit 19];

- (20. Jeng et al., "The Use Of Aryl Azido ATP Analogs As PhotoAffinity Labels For Myosin ATPase," J. Supramolecular Structure 3:448-468 (1975) [Exhibit 20];
- 21. Gottikh et al., "The General Synthetic Route To Amino Acid Esters Of Nucleotides And Nucleosides-5'-Triphosphates And Some Properties Of These Compounds," Tetrahedron 26:4419-4433 (1970) [Exhibit 21];
- (22. Biochemistry, Third Edition, Stryer, L., Editor, pages 96-97 W.H. Freeman and Co., New York (1988);

The above-referenced twenty-two (22) references [Exhibits 1-22] were cited in a European opposition proceedings involving European patent, No. EP 0 286 898 B1, granted on a divisional application with claims to a different invention from those pending in the present application.

Eight (8) exhibits, namely Exhibits 2, 6-7, 9, 12, and 15-17 were previously cited or made of record in this application in some form, and are therefore not being included on accompanying Form PTO-1449. Specifically, Exhibit 2 was cited in the Declaration of Dean L. Engelhardt In Support Of Adequate Description and Enablement submitted as an Exhibit to An Amendment Under 37 CFR 1.116 filed 11/24/97. Exhibit 9 was cited in the Declaration of Dr. Ann Sodja in support of Applicants' January 18, 2001 Amendment Under 37 CFR 1.116. The remaining exhibits previously made of record in this application, namely, Exhibits 6-7, 12, 15 and 17 were cited in either an Information Disclosure Statement or a Supplemental Information Disclosure Statement submitted in connection with this pending application. Kourilsky et al, GB 2019,408 (Exhibit 6), was previously cited in the October 4, 1994 Office Action issued in the immediate parent application, serial no. 08/046,004, filed April 9, 1993. Applicants addressed this document both in their September 18, 1995 Second Preliminary Amendment (pages 14-16) and in their September 20, 1995 Supplemental Amendment to Applicants' September 18, 1995 Second Preliminary Amendment. Exhibit 16, Kourilsky et al, German Patent DE 29 15 082, is related to the above-discussed Kourilsky Great Britian Patent, No. 2 019,408 (Exhibit 6) by virtue of sharing the same priority information.

A completed Form PTO-1449 listing the accompanying remaining fourteen (14) Exhibits, namely, Exhibits 1, 3-5, 8, 10-11, 13-14, and 18-22 is also attached hereto as Exhibit 23.

By this voluntary citation of art, Applicants and their attorney are requesting that the

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documents be made of record in the instant application.

The above citation of references is not a representation that these documents constitute a complete or exhaustive listing, nor that the above listing necessarily includes the closest or most relevant references, nor are these documents necessarily a complete listing of all references known to Applicants or their attorney. It is simply a voluntary citation of references made in good faith, which is not intended to serve in any way as a substitute for the Examiner's own search.

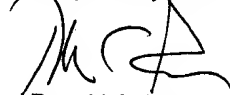
In view of the general and specific features described and claimed in the present application, Applicants respectfully submit that the present invention is neither suggested nor disclosed by the documents referred to above and is thus patentably distinct thereover.

Applicants do not believe, and do not submit, by the citation of these references, that these references, either by themselves or in combination with other references, render the invention prima facie obvious under the new duty of disclosure rules.

Applicants respectfully request that the Examiner make the above-submitted documents of record in the instant application. Applicants further request that the Examiner consider these documents as any of them may relate to the instant application.

The fee under 37 C.F.R. §1.17(p) for filing this Information Disclosure Statement is \$180.000. The Patent and Trademark Office is hereby authorized to charge the amount of this fee (and any other fees in connection with this IDS) to Deposit Account No. 05-1135, or to credit any overpayment thereto.

Respectfully submitted,



Ronald C. Fedus
Registration No. 32,567
Attorney for Applicants

ENZO DIAGNOSTICS, INC.
c/o Enzo Biochem, Inc.
527 Madison Avenue, 9th Floor
New York, New York 10022
Tel. (212) 583-0100

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FOREIGN PATENT DOCUMENTS

[illegible]

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

		Organic Chemistry of Nucleic Acids, Part B., Kochetkov, N.K. and Budovskii, E.I., Editors, Chapter 9, pages 449-477, Plenum Press, London & NY (1972)
		Rozovskaya, T.A. et al., <u>Molkulyarnaya Biologiya</u> 11(3):598-610 (1977)
		Petrov, A. I. And Sukhorukov, B.I., <u>Nucleic Acids Research</u> 8(18):4221-4234 (1980)
		Hiratsuka, T. and Uchida, K., <u>Biochimica et Biophysica Acta</u> 320:635-647 (1973)
EXAMINER		DATE CONSIDERED
<p>*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>		

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FOREIGN PATENT DOCUMENTS													
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION
													YES

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		Saffhill R. and Hall, J.J., <u>Carbohydrates Nucleosides Nucleotides</u> 8:573-583 (1981)
		Erlanger B.F. and Beiser, S.M., <u>Proc.Natl.Acad.Sci.</u> 52:68-74 (1964)
		Suzuki S. et al., <u>Bioinorganic Chemistry</u> 3:281-293 (1974)
		Jeng et al., <u>J. Supramolecular Structure</u> 3:448-468 (1975)
		Gottikh et al., <u>Tetrahedron</u> 26:4419-4433 (1970)
		<u>Biochemistry, Third Edition</u> , Stryer, L., Editor, pages 96-97, W.H. Freeman and Co., New York (1988)

DATE CONSIDERED

***EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.